DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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OCT 26 1998

WARNING LETTER

CERTIFIED MAIL
·RETURN RECEIPT REQUESTED

Abi Schwartz, Owner
Atlas Medical, Inc.
Murray Hill Station
P.O. Box 1426
New York, New York 10156

Re: Chemstrip 10 Reagent Strips for Urinalysis and/or
Bayer Multistix 10SG Reagent Strips for Urinalysis
Labeled for Sale outside the United States

Dear Mr. Schwartz:

This letter concerns the illegal distribution of Chemstrip 10 Reagent Strips for Urinalysis, which are manufactured by Boehringer Mannheim, Mannheim Germany and/or Bayer Multistix 10SG Reagent Strips for Urinalysis manufactured by Bayer Inc. Bridgend, Wales, U.K.

On April 29, 1998, the Food and Drug Administration (FDA) sent you a letter concerning the distribution of the above listed reagent strips for urinalysis. We have not received your response on this issue, and the letter was not returned.

Under a United States Law, the Federal Food, Drug, and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition.

The FDA is concerned about the distribution of these Canadian-labeled urine test strips. The manufacturers of these products, as evidenced by the labels, intended to sell them only in Canada and not in the United States. Consequently, the manufacturers labeled the products in International System (SI) units that are generally used and recognized in Canada. Because these metric units are not commonly used in the United States, consumers in this country may not be able to appropriately convert and interpret the results generated by the device.

The FDA considers these devices to be misbranded under section 502(f)(1) of the Act, in that the labeling fails to bear adequate directions for use as required by Title 21,

Code of Federal Regulations (21 CFR), Section 809.10, Labeling for in vitro diagnostic products.

The FDA has reason to believe that your firm distributes these devices, see the enclosed Atlas Medical Products price list dated August, 1998, and the invoice to [redacted] showing shipment of Multistix 10SG item # AM2300.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that we may consider this information when awarding government contracts.

There are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter does not address all the obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacture and distribution of medical devices by contacting our Division of Small Manufacturers Assistance at 1(800) 638-2041 or through the internet at http://www.fda.gov.

It is necessary for you to take action on this matter now. Please let this office know within fifteen (15) working days from the date of this letter what steps you are taking to correct the problem. Failure to respond to this letter may result in further action by the Agency.

If you have any questions about the content of this letter, please feel free to contact Robert G. Brett, Consumer Safety Officer at (301) 594-4588 or fax (301) 594-4636.

Sincerely yours,

for Adrianne Gold

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: as stated